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**EUROPEAN PATENT APPLICATION**

21 Application number: 82105128.1

51 Int. Cl.<sup>3</sup>: **A 61 F 13/02**

22 Date of filing: 11.06.82

30 Priority: 10.06.81 US 272149

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43 Date of publication of application: 15.12.82  
Bulletin 82/50

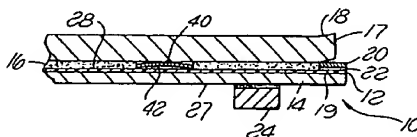
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64 Designated Contracting States: **BE CH DE FR GB IT LI NL SE**

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54 Delivery system for adhesively affixed copolymer medical coverings.

57 A delivery system for adhesively affixed copolymer medical coverings such as adhesive bandages, surgical drapes, medical dressings and the like includes a film sheet disposed on and supported by a film sheet carrier. A transfer adhesive is disposed on all but one edge of a transfer sheet which is then positioned on the film sheet surface opposite the film sheet carrier with a release sheet remaining in place until affixation to a subject to cover and protect the transfer adhesive. The one edge of the transfer sheet without adhesive provides a grasping edge whereby the release sheet can be easily removed prior to affixation to the subject. A pull strip is affixed to one edge of the film sheet to facilitate removal of the film sheet from the subject after use. A carrier removal tab is affixed to the back of the film sheet carrier to facilitate its separation from the film sheet after affixation of the film sheet to the subject.



**EP 0 066 899 A2**

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BACKGROUND OF THE INVENTION

1  
2  
3       The present invention relates to adhesively affixed  
4 copolymer medical coverings and in particular to a delivery  
5 system for enabling an adhesively attachable copolymer medical  
6 covering to be affixed to a subject without clinging, adhering  
7 or sticking to itself and which enables substantially the  
8 entire surface of the copolymer medical covering to be positioned  
9 in adhesive contact with the subject.

10  
11       The use of polyurethane or other thin copolymer films in  
12 medical applications such as for surgical drapes, wound  
13 dressings, bandages, and the like, are known. For example,  
14 one polyurethane film is presently marketed under the trademark  
15 "Op-Site" by Smith & Nephews. This product is disclosed in  
16 Hodgson Patent No. 3,645,835 issued February 29, 1972. The  
17 covering disclosed in the Hodgson patent includes an adhesively  
18 covered film sheet made of polyurethane or other copolymer.  
19 The adhesive is applied to one surface of the polyurethane film  
20 and is thereafter covered by a suitable protector material.  
21 The protector material or layer remains in place until just  
22 prior to affixation to the subject.

23  
24       The film is adhesively affixed to the subject by first  
25 peeling a small portion of the protector material from the  
26 adhesive and then affixing the exposed adhesive to the body

1 of the subject. Thereafter the adhesive and polyurethane is  
2 progressively and continuously pressed against the body of  
3 the biological subject as the backing paper is progressively  
4 removed.

5  
6 This prior art delivery system thus left the back side  
7 of the polyurethane film sheet exposed and susceptible  
8 to germs, dirt and the like coming in contact with the back  
9 of the polyurethane film sheet. Additionally, because the  
10 polyurethane film sheet with adhesive is relatively thin and  
11 very flexible, it is impractical if not impossible to remove  
12 the protector entirely and thereafter place the polyurethane  
13 sheet on the subject. Such an application technique results  
14 in the gathering, clinging and self-sticking of portions  
15 of the polyurethane film sheet preventing the sheet from being  
16 affixed smoothly over a part of the body of the biological  
17 subject. To avoid this problem, it is necessary to effect  
18 affixation and removal of the protector from the adhesive  
19 at substantially the same time as above described.

20  
21 Even utilizing the above-described application technique,  
22 however, it is difficult to affix polyurethane sheets having  
23 a thickness of approximately one-half mil. However, limitations  
24 as to the thinness of the polyurethane exist because of the  
25 inability to easily and conveniently apply the adhesively  
26 covered polyurethane film to the body of the subject without

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1 the above-described gathering and self-sticking. The problem  
2 is compounded as the surface area of the film sheet increased  
3 as is required for surgical drape applications even if the film  
4 sheet thickness increased to several mils.

5  
6 Additionally, it is desired to have as thin a sheet of  
7 polyurethane as possible for patient comfort. Specifically,  
8 such a thin polyurethane film stretches and moves with the  
9 body of the subject and allows the skin of the subject to  
10 stretch, contract and fold in a substantially unimpeded manner  
11 while still maintaining the covering over the desired part  
12 of the subject's body.

13  
14 The present invention solves the above application problem  
15 by providing a delivery system whereby a film sheet of  
16 polyurethane or other copolymer material having a thickness  
17 up to several mils or more which is stretchable and which  
18 has adhesive applied to one side may be applied to the body  
19 of a biological subject without gathering or self-adhering.  
20 This result is accomplished by providing a relatively un-  
21 stretchable and rigid film sheet carrier on the surface of  
22 the film sheet opposite the adhesively covered surface where  
23 the film sheet carrier remains in place until after the film  
24 sheet has been affixed to the biological subject. Suitable  
25 means, such as a carrier removal tab, is then provided so  
26 that the film sheet carrier can be easily removed and discarded

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1 leaving only the film sheet affixed by the adhesive to the body  
2 of the biological subject.

3

4 The above-described film sheet not only provides a  
5 substantially nonstretchable and relatively rigid carrier  
6 for the film sheet but also protects the film sheet from  
7 exposure to dirt, germs and the like.

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SUMMARY OF THE INVENTION

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1 The present invention comprises a delivery system for  
2 adhesively attached copolymer medical coverings for covering  
3 parts of the body of a biological subject. The delivery system  
4 in accordance with the invention includes a film sheet for  
5 covering a selected part of the biological subject where the  
6 film sheet has a subject facing surface and an opposite parallel  
7 back surface. The film sheet back surface is releasably joined  
8 to a film sheet carrier. The film sheet carrier is inelastic  
9 and rigid relative to the film sheet but is bendable to conform  
10 generally to the contours of the part of the biological subject.  
11 The film sheet carrier is for the purpose of supporting and  
12 maintaining the film sheet in planar configuration until after  
13 the film sheet is affixed to cover the selected part of the  
14 biological subject. The film sheet carrier is thereafter  
15 removed and discarded. The delivery system further includes  
16 a release sheet and a transfer adhesive disposed for covering  
17 at least a portion of the release sheet. The release sheet  
18 and transfer adhesive are then positioned adjacent the film  
19 sheet so that the transfer adhesive adheres to at least a  
20 portion of the subject facing surface of the film sheet.  
21 Thus, the film sheet is sandwiched between the release sheet  
22 and the film sheet carrier prior to application to the selected  
23 part of the biological subject. In operation, the transfer  
24 adhesive transfers to the film upon removal of the release  
25  
26

1 sheet prior to application of the film sheet to the selected  
2 part of the biological subject. The film sheet is held to  
3 the selected part of the subject by the transfer adhesive.  
4

5 In accordance with the invention, the delivery system  
6 further includes a pull strip which is adhesively attached  
7 along at least a section of one edge of the subject facing  
8 surface of the film sheet. Preferably, at least a section of  
9 the release sheet is transfer adhesive-free with the transfer  
10 adhesive-free section being positioned over the pull strip  
11 whereby at least a portion of the pull strip is free of  
12 transfer adhesive to facilitate grasping and removal of the  
13 film sheet from the biological subject after use.  
14

15 In accordance with the further embodiment of the  
16 invention, the delivery system includes a carrier removal tab  
17 which is adhesively attached to the film sheet carrier for  
18 being grasped and pulled to thereby pull the film sheet carrier  
19 from the back surface of the film sheet after placement of  
20 the film sheet on the selected part of the biological subject.  
21 The carrier removal tab is positioned so that the film sheet  
22 carrier is between the film sheet and the carrier removal tab.  
23 In the preferred embodiment, the carrier removal tab is  
24 relatively rigid compared to the film sheet carrier to  
25 facilitate grasping and pulling.  
26

BRIEF DESCRIPTION OF THE DRAWINGS

1  
2  
3 A complete understanding of the present invention and  
4 of the above and other advantages thereof may be gained from  
5 a consideration of the following description of the preferred  
6 embodiment taken in conjunction with the accompanying drawings  
7 in which:

8  
9 FIGURE 1 is a cross-sectional view of the delivery system  
10 in accordance with the invention with layer thicknesses  
11 exaggerated.

12  
13 FIGURES 2A, 2B and 2C illustrate one method of making  
14 the delivery system shown in FIGURE 1.

15  
16 FIGURES 3A, 3B and 3C illustrate one method by which  
17 the delivery system in accordance with the invention may be  
18 used to adhesively affix a copolymer film sheet medical covering  
19 to a body part of a biological subject.  
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DETAILED DESCRIPTION

1  
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3       The present invention comprises a delivery system for  
4 enabling a film sheet to be adhesively affixed to a selected  
5 part of the body of a biological subject. The invention is  
6 particularly useful in allowing a thin film sheet which is  
7 stretchable and which has an adhesive applied to one side to  
8 be applied without clinging or sticking to itself prior to  
9 affixation. Accordingly, referring to FIGURE 1, a delivery  
10 system 10 for self-adhering copolymer medical covering  
11 comprises a film sheet 12 disposed on a film sheet carrier 14  
12 by any suitable means such as casting or extrusion whereby the  
13 film sheet 12 adheres to the carrier 14 without the necessity  
14 of adhesives.

15  
16       In the preferred embodiment, the film sheet is a  
17 thermoplastic polyurethane having a thickness of about one-half  
18 mil or larger. Films having thicknesses of about one-half mil  
19 are preferably made by casting a solution of the polyurethane  
20 or other copolymer onto a smooth surface such as a release coated  
21 silicon paper. Suitable materials and their production are  
22 described in U.S. Patent No. 2,871,218. The present  
23 invention is particularly useful with copolymer film sheets  
24 because of the tendency of such sheets to gather and  
25 cling to themselves making it impossible to affix such film  
26 / / /

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1 sheets over a selected part of a biological subject. Such  
2 gathering and self-sticking thus prevents a continuous contact  
3 over the selected part of the biological subject allowing  
4 gaps and spaces, in which germs, dirt and other foreign matter  
5 can become trapped. Such unsterile conditions can defeat  
6 the objectives of the Hodgson adhesive material in actual use.  
7

8 The transfer adhesive 16 is deposited over the subject  
9 facing surface 28 of the film sheet 12 by pressing (laminating)  
10 the transfer adhesive 16 on release sheet 17 against film  
11 sheet 12. The delivery system in accordance with the invention  
12 further includes a transfer adhesive initially disposed on a  
13 release sheet 17. Thereafter the release sheet 17 remains in  
14 place to cover and protect the transfer adhesive 16 until a  
15 time just prior to application to the selected part of the  
16 biological subject.  
17

18 The transfer adhesive 16 may be disposed over the  
19 entire surface 28 of the film sheet 12 with the release backing  
20 sheet 17 similarly protecting the entire surface of the  
21 transfer adhesive 16. However, in the preferred embodiment,  
22 the release sheet 17 extends beyond an edge of the transfer  
23 adhesive 16 to form a flap section 18. The flap section 18  
24 enables the release sheet 17 to be readily removed from the  
25 transfer adhesive 16 to expose the transfer adhesive 16  
26 immediately prior to application to the selected part of the

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1 biological subject.

2 In the preferred embodiment, the transfer adhesive 16  
3 is applied to cover only a portion of the subject facing surface  
4 28 of the film sheet 12 with at least an edge region 19 being  
5 left without adhesive covering. This adhesive-free strip or edge  
6 region 19 then provides a region that can be grasped and pulled  
7 to facilitate easy removal of the film sheet 12 from the subject  
8 after use. Of course, other areas of the subject facing surface  
9 may be left without adhesive covering so that a gauze 40 or other  
10 object can be adhesively attached to the film by an adhesive 42  
11 without itself being subsequently covered with transfer adhesive 16

12 In accordance with the invention, the transfer adhesive 16  
13 may be any of a number of well-known transfer adhesives, such as  
14 those disclosed in the Hodgson patent No. 3,645,835 issued  
15 February 29, 1972, which disclosure is hereby incorporated by  
16 reference. The release sheet 17 may be release-coated silicon  
17 or any other suitable release sheet well known in the art.  
18 The film sheet carrier may similarly be a release-coated silicon  
19 paper or preferably is a Mylar sheet which is flexible but  
20 relatively rigid compared with the film sheet 12 and is  
21 relatively unstretchable when compared with the stretchability  
22 of the film sheet 12. Thus, the film sheet carrier 14 serves  
23 as a support for the film sheet 12 until after affixation of  
24 the film sheet 12 to the selected part of the biological  
25 subject. After the film sheet 12 has been affixed to the  
26 biological subject, the film sheet carrier 14 can be removed  
27 since its support function is no longer required.

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1 It will be appreciated that the edge region 19 of the  
2 film sheet 12 may be provided as a pulling section without  
3 any reinforcement. However, in the preferred embodiment and  
4 in particular when the film sheet 12 is thin, a reinforcing  
5 pull strip 20 is laminated along the edge region 19 to thereby  
6 reinforce the edge region 19 and further facilitate removal  
7 of the film sheet 12 from the subject after use. The pull strip  
8 20 may be adhesively affixed along the edge region 19 of the  
9 film sheet 12 utilizing any of a number of available permanent  
10 medical grade adhesives 22 such as medical grade transfer  
11 adhesive No. 1514 produced by 3M Corporation. The flap section 18  
12 of the release backing sheet 16 then extends either partially  
13 or entirely over the pull strip 20. To facilitate removal of  
14 the film sheet carrier 14 from the film sheet after affixation,  
15 a carrier removal tab 24 is provided. The tab 24 is adhesively  
16 affixed to the back of the film sheet carrier 27 utilizing a  
17 suitable permanent adhesive 26 which may, for example, be the  
18 same as the adhesive 22 used to affix the pull strip 20 to the  
19 subject facing surface 28 of the film sheet 12. In the preferred  
20 embodiment, the carrier removal tab 24 has a thickness of between  
21 5 and 10 times the thickness of the film sheet carrier 14 and may,  
22 for example, be a 10-point tag. Such a thickness results in a  
23 carrier removal tab 24 which is relatively rigid compared to the  
24 film sheet carrier 14, thus enabling the carrier removal tab 24  
25 to be grasped and pulled to separate and remove the film sheet  
26 carrier 14 from the film sheet 12 after the film sheet 12 has

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1 been applied to the selected part of the biological subject.

2

3 Referring to FIGURES 2A, 2B, and 2C, the delivery system  
4 for self-adhering copolymer medical coverings may be manufactured  
5 by first casting the polyurethane film 12 on a Mylar backing 14.  
6 The combination of the polyurethane film 12 and Mylar backing 14  
7 is commercially available and may be purchased from any of a  
8 number of different suppliers. A pull strip 20 with the  
9 permanent adhesive 22 on one side is then disposed on the edge  
10 region 19 of the film sheet 12 utilizing suitable laminating  
11 machinery such as the Mark Andy 2100 System produced by Mark  
12 Andy Incorporated of Chesterfield, Missouri.

13

14 After the pull strip 20 has been permanently adhesively  
15 affixed to the edge of the film sheet 12, a release sheet 17  
16 with transfer adhesive 16 disposed over all but a flap section  
17 18 is laminated onto the subject facing surface 28 of the film  
18 sheet 12 as shown in FIGURE 2B so that the layer of transfer  
19 adhesive 16 is laterally adjacent to the previously affixed  
20 pull strip 20. Thus, at least a portion and preferably all  
21 of the top 21 of the pull strip 20 will be free of the transfer  
22 adhesive 16. In such an arrangement, the transfer adhesive 16  
23 is laterally adjacent to the pull strip 20 with the release  
24 sheet 17 covering the transfer adhesive 16 and remaining in  
25 place until just prior to affixation to the selected part of  
26 the biological subject. The transfer adhesive and release

backing may be disposed on the subject facing surface 28 of the film sheet 12 utilizing conventional laminating techniques and machinery and may be affixed in a manner similar to the method by which the pull strip 20 is affixed. In a similar manner a gauze 40 or other object can also be affixed to the film sheet without being covered by transfer adhesive.

Finally, referring to FIGURE 2C, the carrier removal tab 24 is permanently adhesively affixed to the back surface 27 of the film sheet carrier 14 utilizing a laminating technique as above described. It will, of course, be appreciated that the carrier removal tab 24 may be positioned at any location along the back surface 27 of the film sheet carrier 14. The resultant preferred embodiment of the delivery system 10 for self-adhering copolymer medical coverings with the pull strip 20 and the carrier removal tab 24 is thus shown in FIGURE 1.

Referring now to FIGURES 3A, 3B, and 3C, the use of the delivery system in accordance with the invention is illustrated. Specifically, the release sheet 17 is first removed by pulling on the flap section 18. After the release sheet 17 is removed and discarded, the transfer adhesive 16 which remains on the subject facing surface 28 of the film sheet 12 is exposed. The exposed transfer adhesive 16 is then placed over a selected part of a biological subject 32 as shown in FIGURE 3B. The polyurethane is thereby adhesively affixed to the biological subject 32 using the transfer adhesive 16 with the film sheet carrier 14 still in place. Once the film sheet 12 has been

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1 so adhesively affixed, the carrier removal tab 24 is pulled  
2 causing the film sheet carrier 14 to separate from the film  
3 sheet 12. The film sheet carrier 14 is then discarded. The  
4 part of the body of the biological subject 32 will thus be  
5 covered by the polyurethane film sheet 12 which is affixed  
6 by the adhesive 16 in a smooth continuous manner without  
7 the normal problems of gathering and self-sticking of the film  
8 sheet 12 prior to affixation.

9  
10 The film sheet 12 may subsequently be removed by  
11 simply grasping the pull strip 20 and pulling the polyurethane  
12 film sheet 12 from the subject 32 as illustrated in FIGURE 3C.

13  
14 It will be appreciated, of course, that various modifica-  
15 tions and changes may be made in the above-described preferred  
16 embodiments without departing from the essence of the invention.

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1 WHAT IS CLAIMED IS:

1. A delivery system for self-adhering copolymer  
medical coverings for covering parts of biological subjects  
5 comprising:

a film sheet for covering a selected part of the  
biological subject, the film sheet having a subject facing  
surface and a back surface;

a film sheet carrier, the film sheet releasably ad-  
10 hering to the film sheet carrier along the back surface of  
the film sheet, the film sheet carrier being inelastic re-  
lative to the film sheet but bendable to conform generally  
to the contours of the part of the biological subject for  
supporting the film sheet until after the film sheet is  
15 affixed to cover the selected part of the biological sub-  
ject, the film sheet carrier thereafter being removed;

a release sheet;

a transfer adhesive disposed for covering at least a  
portion of the release sheet, the release sheet and transfer  
20 adhesive positioned adjacent the subject facing surface of  
the film sheet whereby the transfer adhesive adheres to at  
least a portion of the subject facing surface so that the  
film sheet is sandwiched between the release sheet and the  
film sheet prior to application to the selected part of the  
25 biological subject and whereby the transfer adhesive  
transfers to the film sheet upon removal of the release sheet  
in preparation for affixation of the film sheet to the se-  
lected part of the biological subject, the film sheet being  
adhesively held to the selected part of the biological  
30 subject by the transfer adhesive.



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25 ~~sheet upon removal of the release sheet in preparation for~~  
26 affixation of the film sheet to the selected part of the biological  
27 cal subject, the film sheet being adhesively held to the  
28 ~~selected part of the biological subject by the transfer adhesive.~~

1           2. The delivery system of Claim 1 further comprising:  
2           a pull strip adhesively attached along at least a  
3 section of one edge of the subject facing surface of the film  
4 sheet.

1           3. The delivery system of Claim 2 wherein at least a  
2 section of the release sheet is transfer-adhesive free, the  
3 transfer-adhesive free section being positioned over the pull  
4 strip whereby at least a portion of the pull strip is free of  
5 transfer adhesive to facilitate grasping and removal of the  
6 film sheet from the biological subject after use.

1           4. The delivery system of Claim 1 wherein at least a  
2 section of the release sheet is transfer-adhesive free, the  
3 delivery system comprising:  
4           a gauze affixed to a section of the film sheet;  
5           an adhesive for affixing the gauze to the section of  
6 the film sheet, the adhesive-free section of the release sheet  
7 being positioned over the gauze.

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1           5. The delivery system of Claims 1, 2, 3 or 4, further  
2 comprising:

3           a carrier removal tab attached to the film sheet carrier  
4 for being grasped and pulled to thereby pull the film sheet  
5 carrier from the back surface of the film sheet after placement  
6 of the film sheet on the selected part of the biological subject,  
7 the carrier removal tab being positioned so that the film sheet  
8 carrier is between the film sheet and the carrier removal tab.

1           6. The delivery system of Claim 5 wherein the carrier  
2 removal tab is permanently adhesively attached to the film sheet  
3 carrier.

1           7. The delivery system of Claim 5 wherein the carrier  
2 removal tab has a thickness at least five times the thickness  
3 of the film sheet carrier.

1           8. The delivery system of Claims 1, 2, 3 or 4 wherein the  
2 film sheet has a thickness less than about one-half mil.

1           9. The delivery system of Claim 1 wherein the film  
2 sheet is polyurethane.

1           10. The delivery system of Claim 1 wherein the film  
2 sheet carrier is Mylar.

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1           11. The delivery system of Claim 1 wherein the film  
2 sheet is stretchable copolymer for conforming to variations in  
3 the contours of the selected part of the biological subject  
4 as the biological subject moves.

1           12. The delivery system of Claim 1 wherein at least a  
2 section of the release sheet is free of transfer adhesive and  
3 the transfer adhesive and release sheet are joined to the  
4 subject facing surface of the film sheet so that an edge region  
5 of the film sheet is free of transfer adhesive when the release  
6 sheet is removed and the film sheet applied to the selected  
7 part of the biological subject.

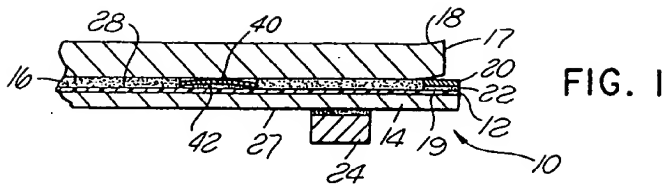


FIG. 1

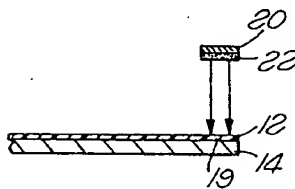


FIG. 2A

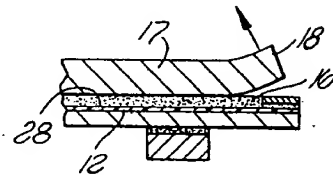


FIG. 3A

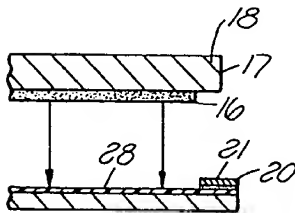


FIG. 2B

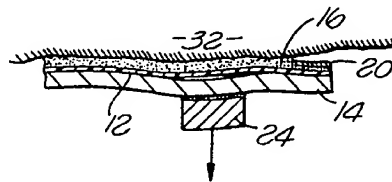


FIG. 3B

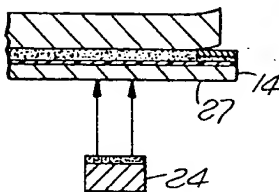


FIG. 2C

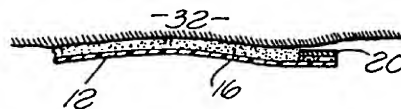


FIG. 3C